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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,045	08/31/2001	Masahiro Sasaki	188-88	7829

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/936,045	Applicant(s) SASAKI ET AL.	
	Examiner MISOOK YU, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-48 is/are pending in the application.
- 4a) Of the above claim(s) 40-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 26 January 2004 is acknowledged. Claims 21-48 are new.

Election/Restrictions

Newly submitted claims 40-48 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the previously examined claims 1-20 were directed to product, more specifically "a functional oral preparation". Claims 40-48 are drawn to method of preventing colon cancer. If method of preventing colon cancer were presented before the first Office action on merits, then those claims would have been restricted as invention group II and claims directed at the product as invention group I because groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT Rule 13.2 and 37 C.F.R. 1.475 define "special technical feature" as those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The special technical feature of the instant first claim i.e. an hydrolyzed product of sericin had been known in the art as the International Search Report indicated (see JP 1-256351, a copy provided in the International Search Report). Also see the art rejection of record in the prosecution history of the instant application.

Thus, the unity between a product and method of using said product lacks unity under PCT Rule 13.2 and 37 C.F.R. 1.475.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; (2) A product and a process of use of said product; (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; (4) A process and an apparatus or means specifically designed for carrying out said process; or (5) A product, a process specially adapted for the manufacture of said product, and an apparatus or means specifically designed for carrying out said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40-48 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claims 40-48 drawn to an nonelected invention.

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Claims 40-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 21-48 are pending. Claims 21-39 are under consideration.

Claim Rejections - 35 USC § 102, Maintained

The rejection under 35 U.S.C. **102(b)** as being anticipated by JP 1-256351 (1989, IDS) is now applied to new claims 21-39 and maintained.

Claims 21-39 are interpreted as drawn to composition suitable for oral administration comprising water-soluble sericin mixture per se. Note claim construction of claim 39; it is written in Markush language.

Applicant argues that: JP 1-256351 is directed to producing food extremely soft and pleasant to the plate by adding drink to **an aqueous solution of silk fibroin and sericin** and then gelling the silk fibroin and sericin; sericin and a beverage, where the sericin used in the claimed invention are water-soluble, not gels; the present invention is a preparation for preventing colon cancer.

The arguments have been fully considered but found unpersuasive because **an aqueous solution of silk fibroin and sericin** is same as water-soluble sericin. In other words, sericin in a beverage is a water-soluble sericin. JP 1-256351 teaches getting to a gel form from water-soluble sericin mixture. Sericin mixture is mixed with juice and so forth, ...then arrive at gel form. JP 1-256351 (English abstract) teaches composition suitable for oral administration comprising sericin derived from silkworm

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cocoons or raw silk. As stated in the previous Office action, the intended use is not given patentable weight for purposes of comparing the claims with the prior art. The claims read on the composition *per se*, whose main ingredient is sericin mixture from silkworm cocoons or thread. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the composition of the prior art does not possess the same material, structural and functional characteristics of the instantly claimed composition. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed composition is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989JP 1-256351 thus anticipates the instantly claimed invention.

The rejection under 35 U.S.C. **102(e)** as being anticipated by US Pat. 6,165,982 (Yamada et al) is applied to new claims 21- 39 and maintained.

Claims 21-39 are interpreted as drawn to composition suitable for oral administration comprising water-soluble sericin mixture *per se*. Note claim construction of claim 39; it is written in Markush language. Claims 31-38 are included in this rejection because the Office's interprets of claim 31 as drawn to composition comprising (1) water-soluble sericin, (2) its hydrolyzed (3) product and mixtures thereof, or (4) a mineral mix. Markush group recites members as being "selected from the group consisting of A, B, and C". See claims rejection under 112, second paragraph for further details on this matter.

Applicant argues that Yamada et al are explicitly directed to inhibition tyrosinase activity; treatment of the gastrointestinal ailments by the claimed invention herein is not disclosed in Yamada et al. The argument has been fully considered but found unpersuasive because the claims are interpreted as drawn to composition suitable for oral administration comprising sericin derived from silkworm cocoons or raw silk and the intended use is not given patentable weight for purposes of comparing the claims with the prior art. The claims read on the composition *per se*, whose main ingredient is sericin mixture from silkworm cocoons or thread. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the composition of the prior art does not possess the same material, structural and functional characteristics of the instantly claimed composition. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed composition is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989JP 1-256351 thus anticipates the instantly claimed invention.

US Pat. 6,165,982 teaches composition suitable for oral administration comprising sericin derived from silkworm cocoons or raw silk. See columns 4-6, and claims 4-15.

Claim Rejections - 35 USC § 103, Withdrawn

The rejection of Claims under 35 U.S.C. 103(a) as being unpatentable over either JP 1-256351 or US Pat. 6,165,982 in view of either Vargas et al (1992, Cancer, vol. 70,

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5 Suppl, pages 1229-35 Abstract only) or Alberts et al (1997, Cancer Epidemiol Biomarkers Prev. vol. 6, pages 161-9) is withdrawn in view of the amendment. The rejected claims are now cancelled and they no longer exist. The rejection of record under 35 U.S.C. 103(a) is not applicable to the new claims.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31-38 are indefinite for being in improper Markush format. MPEP 2173.05(h)) states that proper Markush group recites members as being "selected from the group consisting of A, B, and C". Claim 31 uses Markush group format for claim construction. It is not clear whether (1) water-soluble sericin, (2) its hydrolyzed (3) product and mixtures thereof, and (4) a mineral mix are all alternative species that belong to "at least one ingredient".

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne C Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MISOOK YU, Ph.D.
Examiner
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LARRY R. HELMS, PH.D
PRIMARY EXAMINER